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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,901	09/19/2001	Norman J. Dovichi	45504-019	2915

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EXAMINER

LUDLOW, JAN M

ART UNIT	PAPER NUMBER
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1743
DATE MAILED: 12/17/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/936,901	DOVICI, NORMAN J. VB
Examiner	Art Unit	
Jan M. Ludlow	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-21 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-8, 10-18 and 21 is/are rejected.
- 7) Claim(s) 9, 19 and 20 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 19 September 2001 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 . | 6) <input type="checkbox"/> Other: _____ |

1. Claims 9, 19-20 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

2. Claims 4-8, 13-18, 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 4, last three lines, occurring twice, "to perform the...separation means" is grammatically unclear. In claim 13, it is unclear whether the reverse phase, normal phase, size exclusion, and ion exchange chromatographic separation of parts a and c are subject to high voltage as recited in part d. Claim 15 depends from itself. In claim 21, it is not clear whether or not the valve means are positively recited. The claim has been interpreted as not positively reciting the valve means, and therefore positively reciting only an inlet, a channel network and interface regions including three ports.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application

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being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-2, 4, 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/33989 (WO).

WO teaches a first electrophoresis capillary 56, a second electrophoresis capillary 116 and interface 80 with reagent inlet 84 and waste outlet 76. Detectors 52 and 88 are provided and power supplies 60 and 92 are used to perform the electrophoresis. Detectors include fluorescence detectors (p. 13, line 4) and the types of electrophoresis include isoelectric focusing and sieving (p. 17, lines 20-25). Added

reagents include enzymes and antibodies (p. 20, lines 13-21), which constitute derivatizing agents in that they react with the analytes to form derivative products, such as degradation products and bound complexes. In addition, components can be fluorescently labeled (p. 13-15).

7. Claims 3, 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO as applied to the claims above.

WO fails to explicitly teach the claimed laser detection or order of electrophoretic steps.

It would have been obvious to perform sieving electrophoresis as the second form of capillary electrophoresis in order to classify separated components by molecule weight using a technique taught by WO.

8. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO as applied to claims above, and further in view of Moring.

WO fails to teach adding fluorescent label at the interface.

Moring teaches an interface similar to that of WO. Fluorescent label may be added at the interface (see, e.g., abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the label at the interface in WO in order to add the label at an alternative point in the reaction and separation sequence as taught by Moring.

9. Claims 5-8, 16-18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO as applied to claims above, and further in view of Yeung et al. WO fails to teach a plurality of interfaces in a manifold.

Yeung et al teaches a system for performing chromatography followed by electrophoresis or other separation. A manifold 26 connects channel 90 to valve 22, which is connected to a syringe pump 19, and a variety of reservoirs via ports 53-57 (col. 11, lines 41-59). The manifold is also coupled to interfaces 32 which couple the chromatographic columns 14 to the electrophoresis capillaries 33 and outlet channels coupled to manifold 31. Laser induced fluorescence is used to detect separated components (e.g., col. 21, line 17).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a manifold as taught by Yeung in the apparatus and method of WO in order to perform plural simultaneous separations with reagent addition at the interface as taught by Yeung. It would have further been obvious to use laser induced fluorescence as the fluorescence detection in WO in order to provide an art recognized alternative detection system as taught by Yeung.

10. Claims 1, 4-5, 7-8, 10, 13-14, 17-18, 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Yeung.

Yeung et al teaches a system and method for performing chromatography followed by electrophoresis or other separation. A manifold 26 connects channel 90 to valve 22, which is connected to a syringe pump 19 and a variety of reservoirs via ports 53-57 (col. 11, lines 41-59). The manifold is also coupled to interfaces 32 which couple the chromatographic columns 14 to the electrophoresis capillaries 33 and outlet channels coupled to manifold 31. Laser induced fluorescence is used to detect separated components (e.g., col. 21, line 17).

11. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yeung as applied to claims above, and further in view of Moring.

Yeung fails to teach adding fluorescent label at the interface.

Moring teaches an interface similar to that of Yeung. Fluorescent label may be added at the interface (see, e.g., abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the label at the interface in Yeung in order to add the label at an alternative point in the reaction and separation sequence as taught by Moring.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Khan et al is related to WO 95/33989.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (703) 308-4039. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



Jan M. Ludlow
Primary Examiner
Art Unit 1743

jml
December 12, 2002